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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-855,294	05/15/2001	Carlo Croce	CRO01-NP007	1905

7590

02/25/2003

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EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/855,294

Applicant(s)

Croce et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 3, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 4-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group I (claims 1-3) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that "[i]t is well settled that for an application to be properly restricted, there must be a serious burden on the Examiner", that "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on its merits, even though it include claims to independent or distinct inventions", that "with respect to polynucleotide sequences... a reasonable number of independent or distinct nucleotide sequences, normally ten sequences, to be examined in a single application", and that "at a minimum, the claims of Groups I, IV and XI should be rejoined". This is not found persuasive because MPEP 803.04 alternatively states "[n]ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to each other", and that it "may be necessitated that the reasonable number of sequences to be selected be less than ten". In other words, one sequence is reasonable, due to the exponential growth in the number of sequences now available and required to be checked since the 1996 O.G. notice. Moreover, human proteins/DNA are not murine proteins/DNA, which are not frog proteins/DNA. Further, in regards to Applicants' comments for rejoining all groups, each of the products claimed can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures, they are physically and functionally distinct, and they can be used in different distinct methods, which themselves require different

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goals, starting materials, and different and unique search parameters. It is again pointed out that there is a proper distinction between these groups, since each product and/or method is not required in order for the other to exist. Therefore, the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider each of these separable groups, the requirement is still deemed proper, and is therefore made FINAL.

Claims 4-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

### *Drawings*

2. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

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*Allowable Subject Matter*

3. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Claim Rejections - 35 U.S.C. § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes the single human nucleic acid "encoding a human Nit2 protein" (i.e., SEQ ID NO:8). No other polynucleotides encoding human Nit2 proteins are described within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict what critical nucleotide residues would structurally characterize the genus of polynucleotides encoding human Nit2 polypeptides, as claimed, because it is unknown and not described what structurally constitutes any such allelic variants, derivatives, analogs, or what

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constitutes any functional hybridizable products when none are described. Therefore, the written description requirements under 35 U.S.C. 112, first paragraph are not met.

Applicant is directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding the human Nit 2 protein of SEQ ID NO:1, does not reasonably provide enablement for any biologically equivalent molecule with no structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The name "nucleic acid encoding a human Nit2 protein" is defined on pages 22-25 and 30 of the specification to include "derivatives and analogs", "substitutions, additions or deletions" and biologically "functional equivalent molecules". However, the inclusion of any random mutations within the claimed nucleic acid molecules "encoding a human Nit2 protein" set forth no structural and no functional characteristics. In contrast, the specification fails to disclose what encoded amino acids are critical to maintaining a functional "human Nit2 protein". Therefore, because the specification fails to disclose what residues can be altered and still maintain the desired functional activity of the instant invention, the resultant random mutations to this polynucleotide would be predicted by the skilled artisan to result in encoding an inactive protein.

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For example, Rudinger teaches that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence"(see page 3).

Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification, as to what alterations can be tolerated to maintain a nucleic acid molecule that encodes a functional Nit2 protein, would prevent the skilled artisan from determining whether any Nit2-related polynucleotide could be made that retains the desired function of the instant invention, without undue experimentation to determine otherwise.

### ***Claim Rejections - 35 U.S.C. § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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Claims 1 & 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Donoho et al (WO 01/94566 A2)..

Donoho et al teach an isolated NHP cDNA that encodes the human Nit2 protein of SEQ ID NO:1 (e.g., pgs. 2 & 27; as it relates to claims 1 & 2).

***Oath/Declaration***

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63© and 37 CFR 1.76.

The date the signatures were made is not indicated.



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*Conclusion*

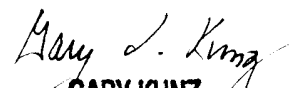
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
February 10, 2003



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